



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA-2015-N-2737]

Medical Devices; Neurological Devices; Classification of the Computerized Cognitive Assessment Aid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the computerized cognitive assessment aid into class II (special controls). The special controls that will apply to the device are identified in this order, and will be part of the codified language for the computerized cognitive assessment aid's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on June 5, 2015.

FOR FURTHER INFORMATION CONTACT: Peter Como, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G242, Silver Spring, MD 20993-0002, 301-796-6919, peter.como@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendment devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to

classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device. On June 24, 2013, Cerebral Assessment Systems, Inc., submitted a request for classification of the Cognivue under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on June 5, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 882.1470.

Following the effective date of this final classification administrative order, any firm submitting a premarket notification [510(k)] for a computerized cognitive assessment aid will need to comply with the special controls named in the final order. The device is assigned the generic name computerized cognitive assessment aid, and it is identified as a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. The computerized cognitive assessment aid is used only as an assessment aid to determine level of cognitive functioning for which there exists other valid methods of cognitive assessment and does not identify the presence or absence of clinical diagnoses. The computerized cognitive assessment aid is not intended as a stand-alone or adjunctive diagnostic device.

FDA has identified the following risks to health associated specifically with this type of device, as well as the measures required to mitigate these risks in table 1:

Table 1.--Computerized Cognitive Assessment Aid Risks and Mitigation Measures

Identified Risk	Mitigation Measure
Equipment malfunction leading to subject injury (shock, burn, or mechanical failure)	Electrical safety testing Labeling
User discomfort (e.g., visual fatigue, stimulus-induced nausea)	Labeling
Incorrect result, inclusive of: <ul style="list-style-type: none"> False positive--cognitive impairment when, in fact, none is present False negative--cognitive impairment when, in fact, cognitive impairment is present 	Hardware and software verification, validation, and hazard analysis Labeling

FDA believes that the following special controls, in addition to the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness:

- The technical parameters of the device's hardware and software must be fully characterized and be accompanied by appropriate non-clinical testing:

- Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.
- Software, including any proprietary algorithm(s) used by the device to arrive at its interpretation of the patient's cognitive function, must be described in detail in the Software Requirements Specification (SRS) and Software Design Specification (SDS). Appropriate software verification, validation, and hazard analysis must be performed.
- The device must be designed and tested for electrical safety.
- The labeling must include:
 - A summary of any testing conducted to demonstrate how the device functions as an interpretation of the current level of cognitive function. The summary of testing must include the following, if available: Any expected or observed adverse events and complications; any performance measurements including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) per the device intended use; a description of the repeatability of measurements; a description of how the cut-off values for categorization of measurements were determined; and a description of the construct validity of the device.
 - A warning that the device does not identify the presence or absence of clinical diagnoses.
 - A warning that the device is not a stand-alone diagnostic.
 - The intended use population and the intended use environment.
 - Any instructions technicians must convey to patients regarding the administration of the test and collection of cognitive test data.

Computerized cognitive assessment aids are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device; see 21 CFR 801.109 (Prescription devices).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the computerized cognitive assessment aid they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E regarding premarket notification submissions have been approved under OMB control number 0910-0120,

and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910-0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. DEN130033: De Novo Request per 513(f)(2) of the Federal Food, Drug, and Cosmetic Act from Cerebral Assessment Systems, Inc., dated June 24, 2013.

List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882--NEUROLOGICAL DEVICES

1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Add § 882.1470 to subpart B to read as follows:

§ 882.1470 Computerized cognitive assessment aid.

(a) Identification. The computerized cognitive assessment aid is a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. The computerized cognitive assessment aid is used only as an assessment aid to determine level of cognitive functioning for which there exists other valid methods of cognitive assessment and does not identify the presence or absence of clinical

diagnoses. The computerized cognitive assessment aid is not intended as a stand-alone or adjunctive diagnostic device.

(b) Classification. Class II (special controls). The special control(s) for this device are:

(1) The technical parameters of the device's hardware and software must be fully characterized and be accompanied by appropriate non-clinical testing:

(i) Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.

(ii) Software, including any proprietary algorithm(s) used by the device to arrive at its interpretation of the patient's cognitive function, must be described in detail in the software requirements specification (SRS) and software design specification (SDS). Appropriate software verification, validation, and hazard analysis must be performed.

(2) The device must be designed and tested for electrical safety.

(3) The labeling must include:

(i) A summary of any testing conducted to demonstrate how the device functions as an interpretation of the current level of cognitive function. The summary of testing must include the following, if available: any expected or observed adverse events and complications; any performance measurements including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) per the devices intended use; a description of the repeatability of measurements; a description of how the cut-off values for categorization of measurements were determined; and a description of the construct validity of the device.

(ii) A warning that the device does not identify the presence or absence of clinical diagnoses.

(iii) A warning that the device is not a stand-alone diagnostic.

(iv) The intended use population and the intended use environment.

(v) Any instructions technicians must convey to patients regarding the administration of the test and collection of cognitive test data.

Dated: August 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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